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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/867,034	05/29/2001	Roberto A. Macina	DEX-0207	DEX-0207 5629	
26259	7590 11/06/2002				
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMI	EXAMINER	
			YU, MISOOK		
			ART UNIT	PAPER NUMBER	
			1642	10	
			DATE MAILED: 11/06/2002	15	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary    Examiner	-		Application No.	Applicant(s)				
## MISCOK YU, Ph.D.   1642  ## The MAILING DATE of this communication appears on the cover sheet with the correspondence address  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ③ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  **Extensions of them may be available under the powdence of 3 CFR 1.13(e). In no event, however, may a reply be timely filled the period for reply specified above is lies than they (30) days, a reply within the statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above, the mainmun statutory pariod will apply and will expire 35 (6) (MONTINS from the mailing daile of this communication. Property within the statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above, the mainmun statutory pariod will apply and will expire 35 (6) (MONTINS from the mailing daile of this communication. Property within the state of the schemication, even if themsy flexible.  **If the period for reply specified above, the mainmun statutory pariod will be statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above, the mainmun statutory pariod will be statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above, the mainmun statutory pariod will be statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above, the mainmun statutory pariod will be statutory minimum of thiny (30) days will be considered timely.  **If the period for reply specified above is lies than the period for reply will be statutory minimum of the period for reply to the statutory minimum of the period for reply will be period to the period to the period for reply to the statutory minimum of the period for the perio	Office Action Summary			MACINA ET AL.				
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1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9,10,11 .  4) Interview Summary (PTO-413) Paper No(s)  5) Notice of Informal Patent Application (PTO-152) 6) Other: .	2) Notice	e of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal	· · · · · · · · · · · · · · · · · · ·				

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The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

#### **DETAILED ACTION**

This application contains claim drawn to nonelected species with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected species or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

## Allowable Subject Matter

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Claim Rejections - 35 USC § 112

Claim 1 **remain rejected** for the reasons set forth in the prior Office Action pages 3-5 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5, does not reasonably provide enablement for any other CGS, defined as nucleotides molecules that have 95 % identity to SEQ ID NO:5. Applicant argue that the amended claim is enabled now because the claim no longer recites "variant" but this argument is not persuasive because the claim is still drawn to variant of SEQ ID NO:5 now defined as "95 % identity" to SEQ ID NO:5. In light of the teachings of the specification at page 1 lines 19 and 20 as well as page 3 lines 28-30 that says that CSG means polynucleotides which due to degeneracy in genetic coding, comprise variations in nucleotide sequence, the claims are interpreted as drawn to SEQ ID NO:5 and its allelic variants. As stated before in the previous Office Action, the art recognizes that use of a human gene as a cancer marker is unpredictable. Sasaki et al (Biochem Biophys Res Commun 2002 Sep 27, 297/3:558) teach that slight change, i.e., one nucleotide change (over 99 % identity) in a human gene may contribute cancer development. It is highly unpredictable if any allelic variant of SEQ ID NO:5 could be

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also used as colon cancer marker and causes undue experimentation to practice the full scope of the claims.

Claim 1 remains rejected for the reasons set forth at pages 8 and 9 of the prior Office Action mailed on 5/21/2002 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant argues that the rejection should be withdrawn because the claim no longer recites "variant". However, the claim is still drawn to genus of CSG (colon specific gene) defined as "95 % identity to SEQ ID NO:5. The specification at page 1 lines 19 and 20 says that CGS is a colon specific gene and at page 3 lines 28-30 says that CSG means polynucleotides which due to degeneracy in genetic coding, comprise variations in nucleotide sequence as compared to SEQ ID NO:5. These definition of CSG indicate that claim 1 is drawn to SEQ ID NO:1 and allelic variants that have 95 % identity to SEQ ID NO:5. As stated in the prior Office Action and reiterated above, the specification provides evidence for only SEQ ID NO:5 that is a CGS. Based on only species, one cannot predict the types of additional species such as an allelic variant. Since the genus includes a large number of unpredictable species, possession of only species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicant adequately describes SEQ ID NO:5.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu October 31, 2002

MARY E. MOSHER PRIMARY EXAMINER GROUP 1880

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